

BECKMAN

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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Alpha₁-Antitrypsin (AAT) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

26 November 1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Alpha₁-Antitrypsin (AAT) Reagent

3.2 **Classification Name**

Alpha-1-antitrypsin immunological test system. (21 CFR § 866.5130)

4.0 **Predicate Device(s):**

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Alpha ₁ -Antitrypsin (AAT)	Beckman Alpha ₁ -Antitrypsin (AAT)	Beckman Instruments, Inc.	K771603

5.0 **Description:**

The IMMAGE Immunochemistry System AAT Reagent in conjunction with Beckman Calibrator 2, is intended for use in the quantitative determination of alpha₁-antitrypsin concentrations in human serum samples on Beckman's IMMAGE Immunochemistry System.

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6.0 Intended Use:

The IMMAGE Immunochemistry System Alpha₁-Antitrypsin (AAT) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human alpha₁-antitrypsin by rate nephelometry.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System AAT Reagent	Analytic Range	Same as Beckman Alpha ₁ -Antitrypsin reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System AAT Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for AAT.
	Antibody concentration	IMMAGE AAT has a higher antibody concentration than the Beckman Alpha ₁ -Antitrypsin reagent

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Reagent on the Array® 360 System to the IMMAGE System Reagent.

Method Comparison Study Results
IMMAGE Alpha₁-Antitrypsin (AAT) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE AAT Reagent	serum	1.007	-3.88	0.995	130	Beckman Array Systems AAT

Stability Study Results

Reagent	Product Claim
IMAGE AAT	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

TYPE OF PRECISION	SAMPLE	Data Points*	Test Mean Value (mg/dL)	SD (mg/dL)	% CV
Within Run	Serum Level 1	80	70.1	1.87	2.7
	Serum Level 2	80	296	6.2	2.1
	Serum Level 3	80	509	15.9	3.1
Total	Serum Level 1	80	70.1	2.33	3.3
	Serum Level 2	80	296	8.2	2.8
	Serum Level 3	80	509	16.4	3.2

TYPE OF PRECISION	SAMPLE	Data Points*	Test Mean Value (mg/dL)	SD (mg/dL)	% CV
Within Run	Low Serum Level 1	30	10.9	0.36	3.3
	Low Serum Level 2	30	44.3	0.72	1.6
Total	Low Serum Level 1	30	10.9	0.40	3.7
	Low Serum Level 2	30	44.3	0.73	1.6

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.